

**What is Claimed Is:**

1. A method of treating a bacterial infection in a human in need thereof which method comprises administering to said human a dosage of a therapeutically effective amount of amoxycillin in the range of 1900 to 2600 mg, at a dosage regimen interval of about 12 h.
2. The method according to claim 1 in which the dosage regimen provides a mean plasma concentration of amoxycillin of 4  $\mu\text{g/mL}$  for at least 4.4 h and a mean maximum plasma concentration ( $C_{\text{max}}$ ) of amoxycillin of at least 12  $\mu\text{g/mL}$ .
3. The method according to claim 1 in which the dosage regimen provides a mean plasma concentration of amoxycillin of 4  $\mu\text{g/mL}$  for at least 4.8 h and a mean maximum plasma concentration ( $C_{\text{max}}$ ) of amoxycillin of at least 16  $\mu\text{g/mL}$ .
4. The method according to claim 1 in which the dosage regimen provides a mean plasma concentration of amoxycillin of 8  $\mu\text{g/mL}$  for at least 4.4 h.
5. The method according to claim 1 in which the dosage is delivered from an immediate release formulation.
6. The method according to claim 5 in which the dosage is 2000, 2250 or 2500 mg of amoxycillin.
7. The method according to claim 6 in which the dosage is provided as a single tablet, or as a number of smaller tablets, may be the same or different.
8. The method according to claim 1 in which the dosage is delivered from a modified release formulation.
9. The method according to claim 8 in which the dosage is provided as a number of tablets, which may be the same or different.
10. The method according to claim 8 in which the dosage is 2000, 2250 or 2500 mg of amoxycillin.

11. The method according to claim 1 in which the infection is caused by the organisms *S pneumoniae* (including Drug Resistant and Penicillin Resistant *S pneumoniae*), *H influenzae*, *M catarrhalis* and/or *S pyogenes*.
- 5 12. A method of treating a bacterial infection in a human in need thereof which method comprises administering to said human a dosage of a therapeutically effective amount of amoxycillin in the range 1400 to 1900 mg, at dosage regimen interval of about 12 h, such that the dosage regimen provides a mean plasma concentration of amoxycillin of 4 µg/mL for at least 4.4 h, and a mean maximum  
10 plasma concentration (Cmax) of amoxycillin of at least 12 µg/mL.
13. The method according to claim 12 in which the dosage regimen provides a mean plasma concentration of amoxycillin of 4 µg/ml for at least 4.8 h and a mean  
15 maximum plasma concentration (Cmax) of amoxycillin of at least 16 µg/ml.
14. The method according to claim 12 in which the dosage is delivered from a modified release formulation.
- 20 15. The method according to claim 12 in which the dosage is 1500 or 1750 mg of amoxycillin.
16. The method according to claim 12 in which the infection is caused by the organisms *S pneumoniae* (including Drug Resistant and Penicillin Resistant *S pneumoniae*), *H influenzae*, *M catarrhalis* and/or *S pyogenes*.  
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17. An immediate release pharmaceutical formulation comprising from 950 to 1300 or 1900 to 2600 mg amoxycillin, in combination with pharmaceutically acceptable excipients or carriers.  
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18. An immediate release pharmaceutical tablet formulation according to claim 17 comprising 1000 mg ±5% amoxycillin in combination with pharmaceutically acceptable excipients or carriers.
- 35 19. An immediate release pharmaceutical formulation according to claim 17 in the form of a single dose sachet comprising 2000, 2250 or 2500 mg ±5% amoxycillin or

the corresponding half quantities thereof, in combination with pharmaceutically acceptable excipients or carriers.

20. An immediate release formulation according to claim 17 in the form of a dispersible tablet or a chewable tablet, effervescent dispersible or effervescent chewable tablet comprising 2000, 2250, or 2500 mg amoxycillin or the corresponding half quantities thereof, in combination with a chewable base and, if effervescent, an effervescent couple, and other pharmaceutically acceptable carrier or excipient.

21. A modified release pharmaceutical formulation comprising an immediate release phase and a slow release phase; the immediate release phase comprising a first part of amoxycillin formulated with pharmaceutically acceptable excipients which allows for immediate release of the first part of amoxycillin, to form an immediate release phase, and the slow release phase comprising a second part of amoxycillin formulated with a release modifying pharmaceutically acceptable excipient, to form a slow release phase.

22. The modified release formulation according to claim 21 which has a biphasic profile with respect to amoxycillin.

23. The modified release formulation according to claim 21 which has an AUC value which is at least 80% of that of the corresponding dosage of amoxycillin taken as a conventional (immediate release) tablet(s), over the same dosage period.

24. The pharmaceutical formulation according to claim 21 in which the ratio of amoxycillin in the immediate and slow release phases is from 3:1 to 1:3.

25. The pharmaceutical formulation according to claim 21 comprising a unit dosage in the range 700 to 1300 mg amoxycillin or 1400 to 2600 mg.

26. The pharmaceutical formulation according to claim 25 in which the unit dosage is: 1000, 875 or 750 mg  $\pm 5\%$  amoxycillin; or 2000, 1750 or 1500 mg  $\pm 5\%$  amoxycillin, in combination with pharmaceutically acceptable excipients or carriers.

27. The pharmaceutical formulation according to claim 26 which is a tablet formulation.

28. The pharmaceutical tablet according to claim 27 comprising 1000 mg  $\pm$ 5% amoxycillin in which the immediate release phase comprises about 563 mg  $\pm$ 5% amoxycillin and the slow release phase comprises about 438 mg  $\pm$ 5% of amoxycillin.
29. The pharmaceutical formulation according to claim 21 in which the amoxycillin of the slow release phase consists essentially of crystallised sodium amoxycillin.
30. The pharmaceutical formulation according to claim 21 which is a layered tablet comprising an immediate release layer comprising amoxycillin and a slow release layer comprising amoxycillin and a release retarding excipient which tablet:
- (a) is a bilayered tablet;
  - (b) comprises at least three layers, including an immediate release and a slow release layer, and comprising at least 275 mg of amoxycillin in the immediate release layer phase;
  - (c) comprises at least three layers, including an immediate release and a slow release layer, and in which the release retarding excipient in the slow release layer comprises xanthan gum and/or a pharmaceutically acceptable organic acid, or
  - (d) comprises at least three layers, including an immediate release and a slow release layer, and in which the amoxycillin is provided as a mixture of amoxycillin trihydrate and sodium amoxycillin, in a ratio of 3:1 to 1:3.
31. The layered tablet according to claim 30 in which the slow release layer comprises a release retarding excipient which is selected from a pH sensitive polymers; a release-retarding polymer which has a high degree of swelling in contact with water or aqueous media; a polymeric material which forms a gel on contact with water or aqueous media; a polymeric material which has both swelling and gelling characteristics in contact with water or aqueous media; a hydrocolloid; carbohydrate-based substances, proteinaceous substances, or a mixture thereof.
32. The layered tablet according to claim 31 in which the release retarding gellable polymer is selected from methylcellulose, carboxymethylcellulose, low-molecular weight hydroxypropylmethylcellulose, low-molecular weight polyvinylalcohols, polyoxyethyleneglycols, and non-cross linked polyvinylpyrrolidone, or xanthan gum.

33. The layered tablet according to claim 31 in which the release retarding excipient is xanthan gum.
34. The layered tablet according to claim 33 in which the xanthan gum is present in  
5 from 1 to 25% by weight of the layer.
35. The layered tablet according to claim 30 in which the slow release layer comprises from 70 to 80% of amoxycillin, from 1 to 25% of xanthan gum, from 10 to 20% of fillers/compression aids, and a conventional quantity of a lubricant.  
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36. The layered tablet according to claim 30 in which the slow release phase comprises sodium amoxycillin and in which the slow release layer comprises a pharmaceutically acceptable organic acid present in a molar ratio of from 100:1 to 1:10 (amoxycillin salt to organic acid).  
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37. The layered tablet according to claim 36 in which the pharmaceutically acceptable acid is citric acid present in a molar ratio of about 50:1 to 1:2.
38. The layered tablet according to claim 37 further comprising a release retarding  
20 gellable polymer.
39. The layered tablet according to claim 38 in which the release retarding gellable polymer is xanthan gum.
- 25 40. The layered tablet according to claim 39 in which xanthan gum is present in from 0.5 to 8% by weight of the slow release layer.
- 30 41. The layered tablet according to claim 36 which comprises 1000 mg  $\pm 5\%$  of amoxycillin and which comprises in the slow release layer about 438 mg  $\pm 5\%$  of crystallised sodium amoxycillin, about 78 mg  $\pm 10\%$  of citric acid and about 2% by weight of xanthan gum
- 35 42. The pharmaceutical formulation according to claim 21 in which the immediate release phase is formed from immediate release granules comprising amoxycillin and the slow release phase is formed from slow release granules comprising amoxycillin.

43. The pharmaceutical formulation according to claim 42 which is a single dose sachet, a capsule, a monolith tablet, a dispersible tablet, a chewable tablet, effervescent chewable tablet, or an effervescent dispersible tablet .
- 5 44. A pharmaceutical formulation comprising 1000 mg  $\pm$ 5% amoxycillin, in combination with pharmaceutically acceptable excipients or carriers.
- 10 45. The pharmaceutical formulation according to claim 44 in which the amoxycillin is present as a mixture of amoxycillin trihydrate and sodium amoxycillin in a ratio of 3:1 to 1:3.
- 15 46. A pharmaceutical formulation comprising amoxycillin in which amoxycillin is provided as a mixture of amoxycillin trihydrate and sodium amoxycillin in a ratio of from 3:1 to 1:3.
- 20 47. The pharmaceutical formulation according to claim 46 in which the ratio of amoxycillin trihydrate and sodium amoxycillin is from 3:2 to 2:3.
- 25 48. A pharmaceutical formulation comprising a pharmaceutically acceptable soluble salt of amoxycillin in a slow release phase which further comprises a release retarding excipient which is a pharmaceutically acceptable organic acid present in a molar ratio of from 100:1 to 1:10 (amoxycillin salt to organic acid).
- 30 49. The pharmaceutical formulation according to claim 48 in which the molar ratio is 50:1 to 1:5.
- 35 50. The pharmaceutical formulation according to claim 48 in which the organic acid is citric acid.
51. The pharmaceutical formulation according to claim 48 in which the soluble salt of amoxycillin is sodium amoxycillin.
52. A kit comprising an immediate release formulation comprising amoxycillin, and a slow release formulation comprising amoxycillin (and no potassium clavulanate).
53. Compacted granules for use in a pharmaceutical formulation comprising amoxycillin, a diluent/compression aid, and an organic acid (if amoxycillin is present as a soluble salt thereof) or a release retarding polymer or a mixture thereof.

54. Compacted granules for use in a pharmaceutical formulation comprising sodium amoxycillin, microcrystalline cellulose, and an organic acid or a release retarding polymer or a mixture thereof.
- 5 55. The process for preparing compacted granules according to claim 54 which process comprises the steps of blending together sodium amoxycillin, microcrystalline cellulose, and organic acid or release retarding polymer or mixture thereof, compacting the blend and then milling.
- 10 56. The pharmaceutical formulation according to claim 42 comprising slow release compacted granules comprising amoxycillin, a diluent/compression aid, and an organic acid (if amoxycillin is present as a soluble salt thereof) or a release retarding polymer or a mixture thereof, , and further immediate release compacted granules comprising amoxycillin.
- 15 57. The formulation according to claim 21 having an AUC,  $C_{\max}$ , and  $t_{\max}$  substantially according to Figure 4 (formulation VI or VII).
58. A formulation which is bioequivalent to the formulation of claim 57.